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10/566,400	10/10/2006	Ramon Merce Vidal	284330US0PCT	3489
22850	7590	01/11/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER COPPINS, JANET L	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 01/11/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

## Office Action Summary

**Application No.**

10/566,400

**Applicant(s)**

MERCE VIDAL ET AL.

**Examiner**

Janet L. Coppins

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 12 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 10-15 and 47-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8 and 18-46 is/are rejected.
- 7) ☒ Claim(s) 2,4,8,9,16-19 and 21-46 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

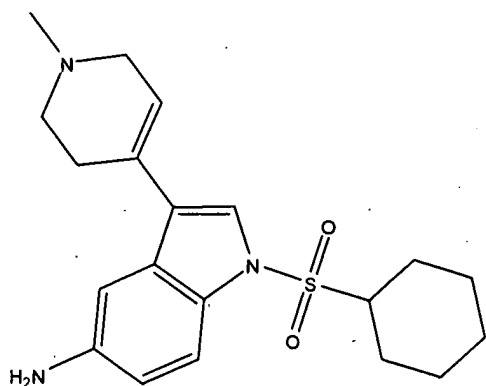
1. Claims 1-74 are pending in the instant application.

#### *Information Disclosure Statement*

2. Applicants' Information Disclosure Statements, filed January 30, 2006, April 26, 2006, and May 8, 2007, have been considered by the Examiner. Please refer to the signed copies of Applicant's PTO-1449 forms submitted herewith.

#### *Election/Restrictions*

3. In the Lack of Unity of October 12, 2007, the Examiner required that Applicants elect a single compound to which the claims must be restricted, in accordance with 37 CFR 1.499. In the response of November 11, 2007, a provisional election was made **with** traverse to prosecute the compound:



5-amino-1-cyclohexanesulfonyl-3-(1-methyl-1,2,3,6-tetrahydropyridine-4-yl)-1H-indole, drawn generically to claims 1-9 (products of formula Ia), claims 16-18 (its process of preparation), claims 19-20 (a medicament), and claims 21-26 (its method of use).

Accordingly, claims 10-15 and 47-74 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

As stated previously, upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. Applicants traverse the finding of Lack of Unity on the grounds that "no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctiveness" and that, "it has not been shown that a burden exists in searching the multiple species."

The Examiner respectfully disagrees with Applicants' traversals. Upon thorough consideration of the claims, the Examiner has determined that a lack of unity of invention exists, as defined in Rule 13.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, **Part 1(a)**, indicates that the application should relate to only one invention, or if there is more than one invention, inclusion is permitted if they are so linked to form a single

general inventive concept.

Annex B, **Part 1(b)**, indicates that "special technical features" means those technical features that as a whole define a contribution over the prior art.

Annex B, **Part 1(c)**, further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter, e.g. product, process, use, apparatus, means, etc.

Annex B, **Part 1(e)**, indicates the permissible combinations of different categories of claims. **Part 1(e(i))** states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible.

Annex B, **Part 1(f)** indicates the "Markush practice" of alternatives in a single claim. **Part 1(f(i))** indicates the technical interrelationship and the same or corresponding special technical feature is considered to be met when: (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B) in Annex B, **Part 1(f)(i-iii)**, the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation from knowledge in the art that all members will behave in the same way. Thus, the technical

relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). **Part 1(f(iv))** indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, taken alone, be considered justification for finding a lack of unity. **Part 1(f(v))** indicates that when dealing with alternatives, it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered, but does not imply that an objection shall be raised.

5. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2, since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a 1-sulfonyl-indole moiety in common, which does not define a contribution over the prior art (**variables excluded**). Attached to the instant office action is a copy of a reference that provides that the technical feature, which can be taken as a whole amongst all the alternatives, as depicted above, is not a 'special technical feature' as defined in PCT Rule 13.2, by failing to define a contribution over the prior art, as it was known in the art prior to the filing of the instant application. Please refer to the attached Radl et al journal article.

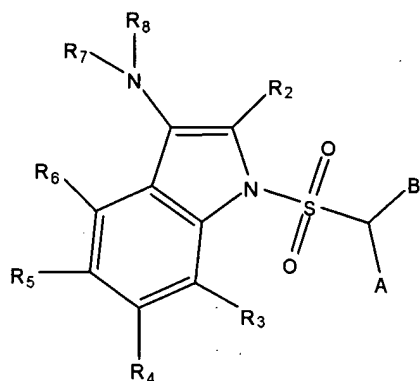
Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

#### *Status of the Claims*

6. Claims 1-74 are pending in the instant application. Claims 10-15 and 47-74, as previously stated, are withdrawn from further consideration by the Examiner as being drawn to

non-elected inventions. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the invention of the elected subject matter is as follows:



Compounds of formula (Ia), depicted in claim 1, wherein R<sup>1</sup> represents -NR<sup>7</sup>R<sup>8</sup>, or a nitrogen-containing heterocycle or heteroaryl; and the remaining variables are as defined.

As a result of the election identified above, the remaining subject matter of claims 10-15 and 47-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b). The withdrawn compounds contain varying functional groups which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. and international classification systems. Therefore the subject matter which are withdrawn from consideration as being non-elected subject matter differ materially in structure and composition and have been restricted properly and a reference that anticipates the elected compound(s) would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 and 18-46 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 1, page 51, lines 10-14, recites, "...optionally in form of one of their stereoisomers, preferably enantiomers or diastereomers, their racemate or in form of a mixture of at least two of their stereoisomers, preferably enantiomers or diastereomers, in any mixing ratio, or a salt thereof, preferably a corresponding physiologically acceptable salt thereof or a corresponding solvate thereof."

Regarding the term "preferably": a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language.



The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "stereoisomers", and the claim also recites "preferably enantiomers or diastereomers, their racemate or in form of a mixture," which is the narrower statement of the range/limitation.

Regarding the "stereoisomers, enantiomers or diastereomers, or racemates," however Applicants have failed to designate any chiral centers, and have neglected to label any such *cis/trans* orientations or any enantiomeric rotations, therefore it is unclear which stereoisomers, or mixtures, etc. Applicants are intending to claim. The Examiner warns that Applicants should exercise caution when amending claim 1, since the Specification also fails to designate any geometric or optical isomers within formula I and does not indicate any chiral centers or orientations, other than a general mention on pages 10, 26, 27, etc.

(b) Regarding claim 18, drawn to a process of preparation, it is unclear what is meant by "suitable solvent" at the end of line 9. Applicants have failed to indicate whether "suitable" describes the physiological or pharmacological properties of the solvent, and which solvents are considered appropriate. The Examiner recommends incorporating the solvents discussed on page 30 of the specification, i.e. "methanol, ethanol, diethyl ether, ethyl acetate, acetonitrile or acetone."

(c) Claims 19 and 20 recite the term "medicament" in line 1, which read on any

prodrug, mixture, or pharmaceutical composition. The Examiner suggests replacing the term "medicament" with the term "pharmaceutical composition," which would then render the claim in compliance with 35 U.S.C. 112, second paragraph. The Examiner cautions that claim 20 is drafted in terms of several future intended uses, and should it be amended, the claim is still directed to a product rather than a method of use. While referring to the contemplated use (i.e. "intended use") of a claimed compound is proper, it is not a limitation and thus of no significance in determining the patentability thereof over the prior art.

(d) Claims 21-46 provide for "the use of" a compound according to claims 1-9, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

***Claim Rejections - 35 USC § 101***

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 21-46 rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

*Claim Rejections - 35 USC § 102*

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1 and 3-8 rejected under 35 U.S.C. 102(b) as being anticipated by Radl et al, Collection of Czechoslovak Chemical Communications. Radl et al teach 1-sulfonyl-indoles that are the same as the instantly claimed compounds according to formula (Ia), please refer to page 284, the indole compound "4" wherein "R<sup>1</sup>" is MeSO<sub>2</sub>, which correspond to RN 269075-58-3 and RN 269075-59-4, for example. The Radl et al compounds are the same as those of the instant claims wherein Applicants' R1 is -NR<sub>7</sub>R<sub>8</sub> wherein R<sub>7</sub> and R<sub>8</sub> are hydrogen; R<sub>2</sub> is a phenylcarbonyl group; R<sub>3</sub>-R<sub>6</sub> are hydrogen; and A and B are an aliphatic radical.

***Claim Objections***

13. Claims 2, 9, 16 and 17 are objected to as being dependent on rejected base claims.
14. Claims 4, 8, 9, 16-19 and 21-46 are also objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

***Conclusion***

14. In conclusion, claims 1-74 are pending in the instant application. Claims 9-10 and 47-74 are currently withdrawn from consideration. Claims 1, 3-8, and 18-46 are currently rejected, and claims 2, 4, 8, 9, 16-19 and 21-46 are objected to.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

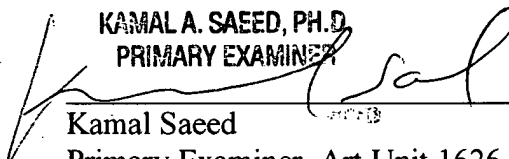
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Janet L. Coppins  
January 1, 2008

  
KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER  
Kamal Saeed  
Primary Examiner, Art Unit 1626